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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,001	06/28/2005	Ludwig J Weimann	ULT1.LU-25	9034

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EXAMINER	
FERNANDEZ, SUSAN EMILY	
ART UNIT	**PAPER NUMBER**
1651	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,001	WEIMANN, LUDWIG J	
	Examiner	Art Unit	
	SUSAN E. FERNANDEZ	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,52-54 and 57-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,52-54 and 57-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed December 15, 2009, has been received and entered.

Claims 1-14, 52-54, and 57-62 are pending and examined on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3-13, 52, 53, and 57-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitragotri et al. (US 5,814,599, listed on 6/28/05 IDS) in view of Royds et al. (US 5,466,465, listed on 6/28/05 IDS), and Unger et al. (US 5,580,575, listed on 6/28/05 IDS).

Mitragotri et al. discloses "a method for enhancing delivery of a drug across the skin comprising applying the drug encapsulated in a liposome or polymeric microparticle to the skin in a pharmaceutically acceptable carrier...and applying ultrasound at a frequency of between 20 kHz and less than 10 MHz at an intensity not causing any irreversible skin damage for a period of time effective to deliver the drug encapsulated in the liposome or microparticle across the skin in a desired drug dosage" (claim 1). It is noted that the ultrasound frequency meets the limitation of ultrasound frequency recited in instant claims 6 and 52.

Mitragotri et al. differs from the claimed invention in that it does not expressly disclose that the medium for holding the microparticles is placed on a surface of a patch adjacent to the skin.

Royds et al. teaches a transdermal drug delivery system (abstract), hence a patch. Figure 1 presents in detail a transdermal patch (column 4, lines 30-32). The patch contains a matrix 20 carrying microencapsulated particles of the drug to be delivered (column 4, lines 56-65) and an adhesive layer 16 (column 4, lines 45-48). In the operation of the drug delivery system, the drug leaches from the particles into the matrix 20 for subsequent passage through the skin of the user (column 5, lines 10-12). As the matrix is formulated to absorb several times its own weight in water given the compounds present in the matrix (column 4, lines 56-61), the matrix holding the microcapsules include skin permeation enhancers (as they would foster hydration of the skin area, fostering release and adsorption of the drug, see column 4, lines 53-55).

At the time the invention was made, it would have been obvious to the person of ordinary skill in the art to have placed the medium for holding the microparticles of the Mitragotri invention on a surface of a patch adjacent to the skin when practicing the Mitragotri invention. One of ordinary skill in the art would have been motivated to do this since Royds et al. demonstrates that the contents of microencapsulated particles can be delivered from a patch for transdermal drug delivery. It would have been obvious to have included skin permeation enhancers in the medium for holding the microparticles of the Mitragotri invention since Royds et al. teaches that they are suitable for inclusion in a transdermal drug delivery system.

Mitragotri et al. also differs from the claimed invention in that it does not teach that the ultrasonic energy applied is at a resonant frequency for certain or all the microparticles.

Unger et al. discloses a drug delivery system involving microspheres comprising a therapeutic drug (abstract). The microspheres are ruptured at the peak resonant frequency using ultrasound (column 17, lines 62-64), wherein the peak resonant frequency will vary depending on the diameter, elasticity, and flexibility of the microspheres (column 18, lines 12-15).

At the time the invention was made, it would have been obvious the person of ordinary skill in the art to have used ultrasound at a resonant frequency for certain or all of the microparticles to rupture them when practicing the Mitragotri invention. One of ordinary skill in the art would have been motivated to do this since microsphere rupture is due to peak resonant frequency, as demonstrated in Unger et al. Therefore, this would allow for selective drug delivery from different sized microparticles. Claim 7 is rendered obvious because it would have been obvious to the person of ordinary skill in the art to have included multiple drugs in a single patch in order to treat a variety of symptoms. As the microparticle diameter affects the peak resonant frequency, different microparticles containing different drugs can be selected for release. A variety of microparticle diameters can be used, thus rendering obvious the diameter recited in instant claim 5.

Furthermore, it would have been obvious to the person of ordinary skill in the art to have included different drugs in the microcapsules, including those recited in claims 8-12 and 58-62, as it would have achieved the predictable result of drug delivery. Furthermore, as noted in the response filed on May 6, 2008, no one specific substance or agent for drug delivery is critical for the operation of the claimed invention. Thus, claims 8-12 and 58-62 are rendered obvious.

A holding of obviousness is clearly required.

Claims 1-14, 52, 53, and 57-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitragotri et al., Royds et al., and Unger et al. as applied to claims 1, 3-13, 52, 53, and 57-62 above, and further in view of Zeimer et al. (US 4,891,043).

As discussed above, Mitragotri et al., Royds et al., and Unger et al. render claims 1, 3-13, 52, 53, and 57-62 obvious. However, they do not expressly disclose that thermal energy is applied to the patch to release the encapsulated drug from the microparticles.

Zeimer et al. teaches a system for selectively releasing materials, such as drugs, at a specific site in the body of an animal (abstract). Lipid vesicles containing the drug are irradiated by a laser beam, thereby heating the lipid vesicles and causing them to rupture (column 4, lines 38-40).

At the time the invention was made, it would have been obvious to have controlled the release of the drugs from the microcapsules in the patch disclosed in Royds et al. by the application of thermal energy (laser beam) to the microcapsules. One of ordinary skill in the art would have been motivated to do this since it would have allowed for the control of drug release, increasing the selectivity of drug release. Thus, claims 2, 14, and 54 are rendered obvious.

A holding of obviousness is clearly required.

Response to Arguments

Applicant's arguments filed December 15, 2009, have been fully considered but they are not persuasive. The applicant asserts that Mitragoti teaches away from the concept of having a patch layer between the skin and the applied drug. However, the section that the applicant points to in Mitragoti (column 5, lines 25-32) is simply a teaching of the preferable site of application

of the drug, rather than the absolute requirements of the application site or the form of the drug. MPEP 2123, Section II indicates that "Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments." Moreover, Mitragoti even teaches that a transdermal patch is suitable as a carrier of the drug (column 4, lines 66-67) and that the drug can be administered as a suspension or a patch (column 4, line 67 through column 5, line 2). Mitragoti clearly provides that the drug can be administered in a patch, and that the drug can be encapsulated (column 5, lines 5-7). Therefore, Mitragoti does not teach away from the claimed invention.

While Royds does not disclose that ultrasound may be used to stimulate release of the drug from a microcapsule, this limitation is met by Mitragoti that teaches that ultrasound application is suitable for drug delivery, and by Unger which teaches that ultrasound at a resonant frequency ruptures microspheres (microspheres can be considered microcapsules). Royds is applied for its teaching of microencapsulated drugs in a transdermal drug delivery system (a patch) as a suitable means for administering drugs.

The teaching of the rupture of gas-filled microspheres in Unger can be applied to the rupture of microcapsules since spheres for drug delivery can be considered equivalent to capsules. The rupture of the microcapsules at a resonant frequency is the only aspect of Unger that is used to modify the teachings of Mitragoti and Royds. It is the combination of Mitragoti and Royds that renders obvious transdermal administration of drugs.

In sum, the rejections of record must therefore be maintained.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN E. FERNANDEZ whose telephone number is (571)272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/
Primary Examiner, Art Unit 1651

Susan E. Fernandez
Examiner
Art Unit 1651

sef